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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,424	11/03/2003	David W. Johnson	047255-5004-US	1511

9629 7590 12/21/2005
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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/698,424

Applicant(s)

JOHNSON ET AL

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1,5 and 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 6-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 29 September 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of invention III (claim 15) without traverse in the 'Response to Restriction Requirement' filed September 26, 2005 has been entered.

Claims 2-4 and 6-19 are under examination.

2. Claims 1, 5 and 20-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 26, 2005.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-4 and 6-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims include the phrase "on average about 8%", for example. The specification fails to provide some standard for measuring the claimed degree and one of ordinary skill in the art could not reasonably apprise of the scope of the invention. See MPEP 2173.05(b).

Claim Rejections - 35 USC § 112, first paragraph – Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-4 and 6-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any alfalfa variety having about 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to adapted commercial varieties grown under the same field growing conditions.

The specification does not provide a written description of the claimed invention with regards to its genetic, morphological and/or physiological characteristics. The specification only provides written description for alfalfa germplasm 'CW 75046', 'CW 83201', 'CW 85029', and 'CW 95026' (see page 11, line 27 to page 12, line 6 and page 25, line 1 to page 45, line 14); however, this description is not clear. For example, alfalfa variety 'CW 85029' is a synthetic variety with 225 parent plants (see page 35, line 8), but there is no genetic, morphological and/or physiological background in the specification regarding these parents. The specification also makes reference to "1,382 French lines", "2,864 elite alfalfa clones", "9,504 alfalfa plants", "numerous elite alfalfa

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populations", and selections from these plants, but none of these are described in terms of their genetic, morphological and/or physiological background (see page 35, line 16 to page 37, line 5). In addition, it is not clear which, if any, of these lines is the intended invention. This lack of written description is also found in alfalfa variety 'CW 83201' (see page 29, line 14 to page 32, line 8), 'CW 85029' (see page 35, line 8 to page 37, line 22) and 'CW 95026' (see page 40, line 3 to page 42, line 20) with regard to the parent plants used in making said alfalfa varieties.

See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession

of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

7. Claims 2-4 and 6-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to any alfalfa variety having about 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to adapted commercial varieties grown under the same field growing conditions.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The specification fails to provide any guidance regarding the genetic, morphological, and/or physiological characteristics of the parents used in the making of

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the claimed invention. The specification only provides guidance for alfalfa germplasm 'CW 75046', 'CW 83201', 'CW 85029', and 'CW 95026' (see page 11, line 27 to page 12, line 6 and page 25, line 1 to page 45, line 14); however, it is not clear which, if any, of these lines are the intended invention.

The specification discloses the use of alfalfa germplasm 'CW 75046', 'CW 83201', 'CW 85029', and 'CW 95026' (see page 11, line 27 to page 12, line 6 and page 25, line 1 to page 45, line 14); however, the specification fails to provide any guidance regarding these lines. For example, alfalfa variety 'CW 85029' is a synthetic variety with 225 parent plants (see page 35, line 8), but there is no genetic, morphological and/or physiological background in the specification regarding these parents. The specification also makes reference to "1,382 French lines", "2,864 elite alfalfa clones", "9,504 alfalfa plants", "numerous elite alfalfa populations", and selections from these plants, but no guidance is provided regarding their genetic, morphological and/or physiological background (see page 35, line 16 to page 37, line 5). In addition, it is not clear which, if any, of these lines is the intended invention. This lack of guidance is also found in alfalfa variety 'CW 83201' (see page 29, line 14 to page 32, line 8), 'CW 85029' (see page 35, line 8 to page 37, line 22) and 'CW 95026' (see page 40, line 3 to page 42, line 20) with regard to the parent plants used in making said alfalfa varieties.

The specification states "[a] synthetic variety is produced by crossing a number of selected genotypes" and "[p]arents are selected on general combining ability, sometimes by test crosses or topcrosses, more generally by polycrosses" (see page 47, lines 14-19). The specification fails to provide any guidance on the general combining

ability of the parents. In addition, the specification states "parents can be selected from such diverse sources as ecotypes, cultivars, and experimental strains" and that the choice of parents "is crucial, for this will determine the performance of the synthetic" (see page 48, lines 9-13). As stated above, the specification fails to provide any guidance regarding the parents.

Applicant defines alfalfa as "any *Medicago* species, including, but not limited to, *M. sativa*, *M. murex*, *M. falcata*, *M. prostrata*, and *M. truncatula*" (see page 11, lines 6-7). It is known in the art that all species from a genus will differ in their genetic, morphological, and/or physiological backgrounds. For example Quiros et al (*The Genus Medicago and the Origin of the Medicago sativa Complex*, Chapter 3, pages 93-124, *In Alfalfa and Alfalfa Improvement*, Hanson et al (ed.), American Society of Agronomy, Monograph No. 29, 1988) teach that the basic genomic number of *Medicago* is $x=8$, but for *M. murex* $x=7$ (see page 93, section 3-2). In addition, Quiros et al teach that there are three ploidy levels found among the *Medicago* spp (see page 94, second paragraph). Therefore, it would require undue experimentation to select all possible alfalfa plants to determine which, if any, would have about 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom.

The development of improved alfalfa varieties is unpredictable. Barnes et al (*Alfalfa germplasm in the United States: Genetic vulnerability, use, improvement, and maintenance*. USDA Tech. Bull. 1571, 21 pages, 1977) teach that differential attractiveness among alfalfas, plant methods and environmental differences can affect

crossing percentages when using bees in natural crossing between two nonbred alfalfa populations (see page 14, third paragraph). Barnes et al also teach that phenotypic selection is effective only for highly heritable characters (see page 15, first paragraph).

Julier et al (Crop Sci. 40: 365-369, 2000) teach that within-population variation can hinder the rate of improvement for polygenetic traits, including lodging (see page 365, second paragraph).

Given the breadth of the claims, the lack of guidance regarding the genetic, morphological and/or physiological background of the parents used to develop the claimed invention, the state of the art, and the unpredictability of the development of improved alfalfa varieties it would require undue trial and error experimentation for one of skill in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102(b)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2-4 and 6-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Moutray (Crop Sci. 23(1): 178-179, 1983).

The claims are drawn to an alfalfa variety having on average about 8% or greater faster recovery after spring green-up or after harvest and on average about 15% or greater more erect stems at late bloom compared to a commercial variety.

The specification states that "Flemish-type alfalfa varieties are characterized as being fast to recover after cutting, early to mature [and] vigorous" (see page 4, lines 19-21).

Moutray et al disclose alfalfa varieties that contain Flemish-type alfalfa, namely 'Apollo' and 'Olympic' (see pages 178-179). The alfalfa varieties disclosed by Moutray would inherently have at least on average about 8% faster recovery after spring green-up or after harvest because of the Flemish-types. The disclosed varieties would also inherently have at least have on average about 15% more erect stems at late bloom as 15% erect stems is defined as 80-89% of stems being lodged (i.e. not erect) (see page 14, lines 3-15). See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

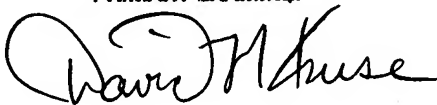
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

November 30, 2005

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written in a cursive style.